

REMARKS

Claims 1, 4-9, 11, 12, 14-31 and 33-53 are pending in the present application. The Examiner asserts that "[t]he inventions are distinct, each from the other..." The Examiner states that Group I (Claims 1, 4-9, 11-12, 14-31 and 33-53) is drawn to a method of promoting smoking cessation comprising administering an effective amount of a pure S,S-enantiomer of reboxetine in combination with an agent selected from the group of nicotine, an antidepressant, an anxiolytic, a nicotine receptor antagonist, or an opioid antagonist, classified in class 514, subclasses 230.5, 279, and 819. The Examiner states that Group I is different from Group II (Claims 31 and 33-48) that is drawn to pharmaceutical compositions comprising a pure S,S-enantiomer of reboxetine and an agent selected from the group of nicotine, an antidepressant, an anxiolytic, a nicotine receptor antagonist, or an opioid antagonist, classified in class 514, subclasses 230.5, 279, and 819. The Examiner contends that the inventions are distinct because the method of promoting smoking cessation in a human can be accomplished with another materially different product, such as nicotine replacement therapies (i.e., nicotine patch, nicotine gum).

We disagree with the Examiner's assertion. Applicants hereby elect with traverse for further prosecution in this application the invention identified in the Office Action as "Group II, (Claims 31 and 33-48) that is drawn to pharmaceutical compositions comprising a pure S,S-enantiomer of reboxetine and an agent selected from the group of nicotine, an antidepressant, an anxiolytic, a nicotine receptor antagonist, or an opioid antagonist, classified in class 514, subclasses 230.5, 279, and 819." Applicants expressly reserve the right to file at a later date one or more divisional applications directed to the subject matter of the non-elected groups.

In the June 15, 2006 Office Action, the Examiner stated that "an election of a species or invention to be examined" must be included. Applicants hereby elect sertraline in order to expedite the prosecution of the subject application. This compound is recited on page 8, line 18 of the subject application.

Applicants traverse the Examiner's Restriction Requirement on the grounds that it is improper because prosecution of the restricted subject matter in one application would not place a serious burden on the Examiner. The criteria for restriction are set forth in M.P.E.P §803 as follows:

There are two criteria for a proper requirement for restriction between patentably distinct inventions:

- (A) The inventions must be independent or distinct; and*
- (B) There must be a serious burden on the examiner if restriction is required. (emphasis added) (internal citations omitted).*

The Examiner alleges that the variously defined inventions are “independent” or “distinct.” However, as § 803 makes clear, independent or distinct inventions must still be examined collectively, i.e., not restricted, unless such examination would impose a serious burden on the examiner. Applicants submit that examination of inventions sharing the same classification imposes no significant burden. Applicants respectfully submit that a single class and three subclasses creates no serious burden imposed on the Examiner to perform a complete search of the defined areas. Applicants respectfully submit that the Examiner has made no showing that prosecuting the claims of the invention in one application would be burdensome. Where there is no serious burden examination of the entire case “must” occur. Here the MPEP is clear:

If the search and examination of the entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions. (MPEP § 803) (emphasis added).

Applicants submit that the Examiner has also erred in applying MEPE 86.05(h). The Examiner contends that the inventions are distinct because the method of promoting smoking cessation in a human can be accomplished with another materially different product, such as nicotine replacement therapies (i.e., nicotine patch, nicotine gum). However, MEPE 86.05(h) states,

“A product and a process of using the product can be shown to be distinct inventions if either or both of the following can be shown: (A) the process of using as claimed can be practiced with another materially different product; or (B) the product as claimed can be used in a materially different process.” (emphasis added)

Hence, Applicants have not claimed every method possible for smoking cessation as the Examiner implies; Applicants have only claimed a method of promoting smoking cessation comprising administering an effective amount of a pure S,S-enantiomer of reboxetine in combination with an agent selected from the group of nicotine, an antidepressant, an anxiolytic, a nicotine receptor antagonist, or an opioid antagonist. Hence, the Examiner’s proffered examples (i.e. nicotine patch, nicotine gum) do not fall within the claimed method. Accordingly, applicants respectfully submit that the Examiner’s characterization of the product and process claims as distinct is improper

Accordingly, Applicants respectfully request that Examiner reconsider and withdraw the present restriction requirement.


In the event that there are any questions relating to this Response or to the application in general, the examiner is requested to telephone the undersigned concerning such questions so that the prosecution of this application can be expedited.

No fee is believed necessary in connection with filing this Amendment. However, if any additional fee is found necessary in connection with filing this Amendment, authorization is hereby given to charge such fee to Deposit Account No. 16-1445.

A favorable response is earnestly solicited.

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Respectfully submitted



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